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K090007

Appendix S2-4
Revised 510(k) Summary

CHAPTER 1. 510(K) SUMMARY

This 510(k) summary of safety and effectiveness for **Jumao Oxygen Concentrator** is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

Table 5-1 General Information

Applicant:	Danyang Jumao Healthcare Equipment Co., Ltd.
Address:	No.89 Shuangfeng Road, Jiepai town, Danyang, Jiangsu, P.R.China
Contact Person:	Qing Wang
Telephone:	(86 511)- 86379811
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Email:	kenwqing@gmail.com
Date of Preparation:	August 10, 2008
Device Name:	JUMAO OXYGEN CONCENTRATOR Model No. JM-07000Hi, JM-07000i, JM-07000
Classification Name:	Portable Oxygen Concentrator
Classification Number:	868.5440
Device Class:	Class II
Product Code:	CAW
Classification Panel	Anesthesiology
Type of submission	Traditional 510K

Intended use:

The intended function and use of the Jumao Oxygen Concentrator is to provide supplemental oxygen to patients with respiratory disorders, by separating nitrogen from room air, by way of a molecular sieve. It is not intended to sustain or support life.

Indications for Use:

The intended function and use of the Jumao Oxygen Concentrator is to provide supplemental oxygen to patients with respiratory disorders, by separating nitrogen from room air, by way of a molecular sieve. It is not intended to sustain or support life.

Device Description

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The **Jumao Oxygen Concentrator** is a Pressure Swing Adsorption (PSA) type oxygen concentrator. The output of oxygen is 0.5 to 5 liter per minute. Room air enters the piston type compressor via a series of filters for removing dust particles. The output compressed air is directed by a pneumatic valve into one of the two sieve beds which is full of adsorption material - molecular sieve. Nitrogen is adsorbed by the molecular sieve as the pressure increases; oxygen flows through the molecular sieve and concentrates at the sieve bed bottom. The enriched oxygen is divided into two streams; one stream enters a storage tank. The pressurized oxygen is regulated down to the suitable pressure, an adjustable flow meter and out to the patient At the same time the second bed is in exhausted status, the molecular sieve desorbs nitrogen as the pressure decreases; another oxygen stream from first bed enters the bottom of the second bed, promotes purging the nitrogen and is exhausted into the atmosphere. Two sieve beds exchange the role of oxygen concentration and continue to produce 90% oxygen to the patient.

Oxygen is delivered to the user by means of standard oxygen supply tubing and a standard nasal cannula, which are not supplied with the device. A standard humidifier bottle may be used with the JM-07000i/ JM-07000 models, if desired.

The JM-07000Hi model incorporates the Humidiflow humidifier to provide humidified oxygen to the user. The Humidiflow attaches to the inlet of the air compressor and to the outlet oxygen used in oxygen concentrators and operates as a mass exchanger to transfer the room air humidity to the patient gas. The Humidiflow humidifier has been cleared by FDA (K062091).

The front panel of the device contains the controls and indicators. These include a standard barb fitting for attaching the oxygen tubing, the adjustable flow meter, a power light indicator, an elapsed time meter, and a standard on/off rocker type power switch.

The basic technology of the JuMao oxygen concentrator is equivalent to the other approved oxygen concentrator. The principles of operation are equivalent to the noted predicate device, Invacare Platinum 5 Oxygen Concentrator by Invacare Corporation, 510(k) K020386.

Predicate Devices:

- Invacare Platinum 5 Oxygen Concentrator by Invacare Corporation, 510(k) K020386.
- LONGFEI LFY-I-5 OXYGEN CONCENTRATOR by Zhejiang longfei industrial co., ltd, K033405
- Drive solstice oxygen concentrator, by Medical depot, K080391
- A&J poca01 oxygen concentrator, by Zhongshan A&J medical equip-ment co., ltd, K071608

Substantial Equivalence Information:

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Substantial Equivalence Comparison Table

	DanYang JuMao Healthcare Equipment CO., Ltd			Invacare Corporation
Product name	JuMao Oxygen Concentrator	JuMao Oxygen Concentrator	JuMao Oxygen Concentrator	Invacare Platinum XL 5-Liter O2 Concentrator with Sens O2
Model No	JM-07000Hi	JM-07000i	JM-07000	IRC5LXO2
510(K) Number	TBD	TBD	TBD	K020386
Concentration levels	same	same	same	95.6% to 87% at all flow rates
Delivery rate	same	same	same	0.5 to 5 LPM
Outlet pressure	same	same	same	5 psi +/-0.5 psi
Alarms	Thermal protection on compressor	Thermal protection on compressor	Thermal protection on compressor	N/A
	same	same	same	oxygen monitor; low-flow
	Low oxygen purity	Low oxygen purity	N/A	N/A
	same	same	same	Power failure
	compressor 40 psi pressure relief valve	compressor 40 psi pressure relief valve	compressor 40 psi pressure relief valve	compressor 35 psi pressure relief valve
Electrical rating	same	same	same	115v 60Hz
Power consumption	same	same	same	4.3 amps average @5L/min(400w)
Filters	same	same	same	Cabinet, out HEPA, Compressor inlet
dimensions	17"W x 28"H x 15"D	17"W x 28"H x 15"D	17"W x 28"H x 15"D	18-3/8"W x 26-3/8"H x 14-3/8"D
Weight (lbs)	same	same	same	52
Operating system	same	same	same	PSA(Pressure swing adsorption)
Sound level	52dBA average	52dBA average	52dBA average	50dBA average
Compressor	GSE-ZW400D2-90 Compressor (Same as K080391)	GSE-ZW400D2-90 Compressor (Same as K080391)	GSE-ZW400D2-90 Compressor (Same as K080391)	Thomas based double wobble
Humidifier	Humidiflow humidifier	same	same	Bottle humidifier

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	(Cleared by FDA, K062091)			
Oxygen sensor	DigiFLO Concentrator Analyzer (Cleared by FDA, K072469)	DigiFLO Concentrator Analyzer (Cleared by FDA, K072469)	N/A	Yes
HEPA Filter	Same	Same	Same	Yes
Intended use	same	same	same	It is to provide supplemental oxygen to patient with respiratory disorders. It is not intended to sustain or support life

Table 5-1 Substantial Equivalence Comparison Table

As the chart above show, **Jumao Oxygen Concentrator** is comparable to its predicate. All devices have the same intended use for the same patient population, extract oxygen from air using the same methodology, provide comparable oxygen purity and are powered in the same manner. There are some small differences in the size, sound level, and compressor pressure between the **Jumao Oxygen Concentrator** and the predicate device, which do not affect the safety and effectiveness of the device.

Safety and Performance Data:
Safety and Performance Testing: The **Jumao Oxygen Concentrator** has been tested in accordance with the following standards:

ASTM 1464-93(2005): Standard Specification for Oxygen Concentrators for Domiciliary Use.
ISO 8359:1996 Oxygen Concentrator for Medical Use-Safety Requirements
IEC60601-1, 2005 Medical Electrical Equipment, Part 1: General requirements for basic safety and essential performance
IEC60601-1-2, 2007 Medical Electrical Equipment-part 1-2: General requirements for safety – collateral standard: Electromagnetic compatibility
FDA Reviewer's Guide: 1993 Reviewer Guidance for Premarket Notifications, November 1993
UL 1431, 2nd ED., 1996 UL Standard for Safety for personal Hygiene and Health Care Appliances Equipment

The safety and performance data found in this submission shows that the **Jumao Oxygen Concentrator** performs as intended and in a manner that is substantially equivalent to the predicate device.

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All the components/materials/process used in the **Jumao Oxygen Concentrator**'s gas path and patient contacting portion are identical to those of the Predicate Devices, see Table S2-1. Therefore, the **Jumao Oxygen Concentrator** meets biocompatibility standards in accordance with FDA Guidance Document FDA's Blue Book Memorandum #G95-1, "Use of international Standard ISO-10993, Biological Evaluation of Medical Devices, Part 1: Evaluation and Testing" (G95-1).

Conclusion:
The data submitted in this 510(K) Premarket Notification supports the finding that this device is substantially equivalent with respect to the intended use, technology, functionality, and safety features to the legally marketed Predicate Device. Therefore, we believe that this device meets the requirement for a "Substantial Equivalence" decision in accordance with the 510(K) guidelines.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Danyang Jumao Healthcare Equipment Company, Limited
C/O Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
Buffalo, Minnesota 55313

JUL 24 2009

Re: K090007
Trade/Device Name: Jumao Oxygen Concentrator
Regulation Number: 21 CFR 868.5440
Regulation Name: Oximeter
Regulatory Class: II
Product Code: CAW
Dated: July 7, 2009
Received: July 8, 2009

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Susan Runner, D.D.S., M.A.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

CHAPTER 4. INDICATIONS FOR USE

510(k) Number (if known): K090007

Device Name: **Jumao Oxygen Concentrator**

Indications for Use:

The intended function and use of the Jumao Oxygen Concentrator is to provide supplemental oxygen to patients with respiratory disorders, by separating nitrogen from room air, by way of a molecular sieve. It is not intended to sustain or support life.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K090007